

REC'D 29 MAR 2005
WIPO POT

70/05/050984

PA 1290291

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

March 04, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111.

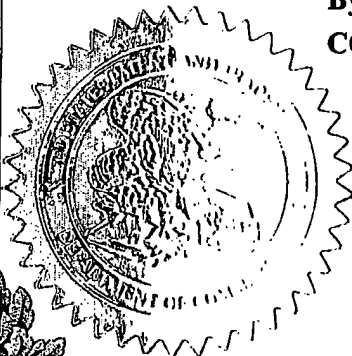
APPLICATION NUMBER: 60/559,321 ✓

FILING DATE: April 02, 2004 ✓

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



P. SWAIN
Certifying Officer

16085 U.S. PTO

Please type a plus sign (+) inside this box → 

Approved for use through 10/31/2002. OMB 0851-0032
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a **PROVISIONAL APPLICATION FOR PATENT** under 37 CFR 1.53(c).

Express Mail Label No. ER 777512382 US

22264 U.S. PTO
 60/559321



040204

| INVENTOR(S) | | | | | |
|--|------------------------|---|--------------|---|--|
| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) | | | |
| David | Becker | Lewistown, PA | | | |
| Terry | Wray | McClure, PA | | | |
| Jeffrey | Hart | Reedsville, PA | | | |
| <input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto | | | | | |
| TITLE OF THE INVENTION (280 characters max) | | | | | |
| ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING | | | | | |
| Direct all correspondence to: CORRESPONDENCE ADDRESS | | | | | |
| <input checked="" type="checkbox"/> Customer Number | | <div style="border: 1px solid black; padding: 2px; display: inline-block;">28159</div> | | <div style="border: 1px solid black; padding: 5px; text-align: center;"> Place Customer Number Bar Code Label here </div> | |
| OR | | Type Customer Number here | | | |
| <input type="checkbox"/> Firm or Individual Name | | W. Brinton Yorks, Jr. | | | |
| Address | | | | | |
| Address | | | | | |
| City | | State | ZIP | | |
| Country | | Telephone | 425-487-7152 | Fax | |
| ENCLOSED APPLICATION PARTS (check all that apply) | | | | | |
| <input checked="" type="checkbox"/> Specification Number of Pages | | <div style="border: 1px solid black; padding: 2px; display: inline-block;">12</div> | | <input type="checkbox"/> CD(s), Number | |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets | | <div style="border: 1px solid black; padding: 2px; display: inline-block;">4</div> | | <input checked="" type="checkbox"/> Other (specify) | |
| <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | | <div style="border: 1px solid black; padding: 2px; display: inline-block;">Express Mail Certificate Receipt Confirmation Postcard</div> | | | |
| METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT | | | | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | | | | <div style="border: 1px solid black; padding: 5px; text-align: center;"> FILING FEE AMOUNT (\$) <div style="border: 1px solid black; padding: 2px; display: inline-block;">160.00</div> </div> | |
| <input type="checkbox"/> A check or money order is enclosed to cover the filing fees | | | | | |
| <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: | | <div style="border: 1px solid black; padding: 2px; display: inline-block;">14-1270</div> | | | |
| <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. | | | | | |
| The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. | | | | | |
| <input checked="" type="checkbox"/> No. | | | | | |
| <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____ | | | | | |

Respectfully submitted,

SIGNATURE



TYPED or PRINTED NAME

W. Brinton Yorks, Jr.

TELEPHONE

425-487-7152

Date

4/2/04

REGISTRATION NO.

(if appropriate)

Docket Number:

28,923

PHUS040173

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

PHUS040173

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT(S): David Becker; Terry Wray; Jeffrey Hart

FOR: "Ultrasonic Intracavity Probe For 3D Imaging"

EXPRESS MAIL CERTIFICATE

"Express Mail" Mailing number: ER 777512362 US

Date of Deposit: April 2, 2004

I hereby certify that this provisional application, including 12 pages of specification and 4 pages of drawings, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents, Mail Stop: Provisional Patent Application, P. O. Box 1450, Alexandria, VA 22313-1450.

Jill Anne Peistrup


(Signature of person mailing paper or fee)

ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING

5 This invention relates to medical diagnostic imaging systems and, in particular, to intracavity probes for three dimensional imaging for ultrasonic diagnostic imaging systems.

10 Intracavity ultrasound probes have been in use for many years for imaging the body from within the body. By imaging from within the body internal organs can be imaged more directly without the need to transmit ultrasound waves through intervening tissue and body structure. For example, transesophageal probes can image the heart and abdominal organs from the esophagus or stomach and avoid the need to send and receive ultrasound through or around the ribs. The present invention relates to intracavity probes inserted in the vagina (IVT probes) or rectum (ICT probes) to image the cervix, uterus, or prostate.

20 In the past, IVT and ICT probes have scanned a two dimensional image region from within the body. This could be done with an array transducer or oscillating single crystal transducer which would scan a sector-shaped area of the body. By curving the elements of an array transducer completely around the distal tip region of the probe, sectors approximating 180° could be scanned. A typical IVT intracavity probe 10 is shown in FIGURE 1. This probe includes a shaft portion 12 of about 6.6 inches (16.7 cm) in length and one inch in diameter which is inserted into a body cavity. The ultrasound transducer is located in the distal tip 14 of the shaft. The probe is grasped and manipulated by a handle 16 during use. At the end of the handle is a strain relief 18 for a cable 20 which extend about 3-

ATL-360

7 feet and terminates at a connector 22 which couples the probe to an ultrasound system. A typical IVT probe may have a shaft and handle which is 12 inches in length and weigh about 48 ounces (150 grams) including the cable 20 and the connector 22.

In recent years ultrasound systems have been introduced with three dimensional (3D) imaging capability and intracavity probes have been designed to perform 3D imaging. Generally this is done by replacing the array transducer which is statically affixed in the distal tip with an array transducer which can be oscillated rapidly in the elevation direction. This oscillation will sweep the image plane being scanned through a volumetric region, acquiring multiple adjacent planar images which can be rendered into a three dimensional image. However, as was the case with earlier oscillating single crystal or annular array transducers, the oscillating array transducer of the 3D probe must be contained within a fluid through which it can oscillate and which is highly transmissive of ultrasound. Generally this fluid will be a water or oil-based solution such as a mineral oil. The fluid is preferably biocompatible so as not to injure or irritate the tissues of the patient in the event of leakage.

These mechanically oscillating 3D array probes will generally house the motor for the oscillation drive within the handle of the probe, thereby keeping it outside the body of the patient. This motor location then mandates a fluid compartment for the oscillating mechanism and transducer which extends through most of or all of the shaft and distal tip of the probe. The fluid will comprise a large portion of the weight of the probe which is located in the

ATL-360

shaft of the probe, causing the center of gravity of the probe to be forward of the handle and in the shaft of the probe. This imbalance makes the intracavity probe unwieldy and difficult to
5 manipulate easily. It would be desirable to reduce the forward weight and balance of the probe so that the 3D intracavity probe is easier to manipulate during a diagnostic procedure.

In accordance with the principles of the present
10 invention a 3D intracavity probe includes an array transducer in the distal tip which is swept to scan a volumetric region. The array transducer is swept by motor which is located in the handle of the probe. The array transducer is contained within a fluid
15 chamber located at the distal tip of the probe and requiring less than 10 cc of fluid. As a result, the center of gravity of the shaft and handle is located in the handle and not the shaft, making the probe easier and more comfortable to hold and manipulate
20 during use.

In accordance with further aspects of the present invention, the array transducer is mounted on an array mount made of a low mass material and displacing space within the chamber which otherwise
25 would be filled with fluid, thereby reducing the fluid volume of the chamber. The shaft and shaft components, except for critical wear surfaces of the array drive mechanism, are also made of low mass materials such as plastics and aluminum.
30 Accordingly, the weight of the probe is less than two-thirds of the weight of prior art 3D intracavity probes.

In the drawings:

FIGURE 1 illustrates a typical intracavity
35 ultrasound probe of the prior art.

ATL-360

FIGURE 2 illustrates a side view of an intracavity probe for three dimensional imaging of the present invention.

5 FIGURE 3 is a side cross-sectional view of a 3D intracavity probe of the present invention.

FIGURE 4 is a perspective view of the tip assembly of a 3D intracavity probe of the present invention.

10 Referring now to FIGURE 2, an intracavity ultrasound probe 30 of the present invention is shown. The probe 30 includes a handle section 36 by which the user holds the handle for manipulation during use. At the rear of the handle is a strain relief 18 for the probe cable (not shown). Extending
15 from the forward end of the handle 36 is the shaft 32 of the probe which terminates in a dome-shaped acoustic window 34 at the distal end through which ultrasound is transmitted and received during imaging. Contained within the distal end of the
20 shaft is a transducer mount assembly 40 which is also shown in the cross-sectional view of the shaft of FIGURE 3 and in the uncovered view of FIGURE 4. A convex curved array transducer 46 is attached to a transducer cradle 48 at the distal end of the
25 assembly 40. The transducer cradle 48 is pivotally mounted by its pivot axis 49 to be rocked back and forth in the distal end of the probe and thereby sweep an image plane through a volumetric region in front of the probe. The transducer cradle 48 is
30 rocked by an oscillating drive shaft 50 which extends from a motor and position sensor 60 in the handle 36 to the transducer mount assembly 40. The drive shaft 50 extends through an isolation tube 52 in the shaft which serves to isolate the moving drive shaft from
35 the electrical conductors and volume compensation

ATL-360

balloon 44 located in the shaft proximal the
transducer mount assembly 40. The drive shaft 50
rocks the cradle by means of two mating bevel gears
54, one at the end of the drive shaft 50 and another
5 on the transducer cradle 48. The motor alternately
drives the drive shaft 50 in one direction of
rotation and then the other, which alternately rocks
the transducer cradle 48 in one direction and then
the other, which sweeps the image plane of the
10 transducer array 46 back and forth through the
volumetric region in front of the distal end of the
probe. The echo signals acquired by the transducer
array 46 are beamformed, detected, and rendered by
the ultrasound system to form a three dimensional
15 image of the volumetric region scanned by the probe.

Because ultrasonic energy does not efficiently
pass through air, the array transducer 46 is
surrounded by a liquid which is transmissive of
ultrasound and closely matches the acoustic impedance
20 of the body which is approximately that of water.
Water-based, oil-based, and synthetic polymeric
liquids may be used. In a constructed embodiment
silicone oil is used. In accordance with the
principles of the present invention, only a small
25 amount of liquid is required in the shaft 32 because
the weight of the liquid can contribute significantly
to the overall weight of the shaft. In some prior
art probes the entire shaft is filled with liquid,
adding substantial weight to the shaft and causing
30 the center of gravity of the handle and shaft to be
located in the shaft. Other prior art probes have
used sizeable elastomeric bags of liquid for the
liquid bath of the transducer array. These
embodiments also locate the center of gravity of the
35 probe in the shaft, which makes the probe ungainly

ATL-360

and difficult to maneuver easily. The liquid used in such embodiments can approach 50 cc, for instance, adding its weight to the probe shaft at the distal end.

5 In accordance with the principles of the present invention the majority of the liquid bath for the transducer array is contained within the transducer mount assembly 40. The only liquid located to the rear of the back surface 42 of the transducer mount
10 assembly 40 (see FIGURE 2) is the small amount of the volume compensation balloon 44. In a constructed embodiment the total amount of liquid in the shaft of the probe is 6.3 cc, of which 95% is contained within the transducer mount assembly 40. Only 0.3 cc of
15 liquid is contained within the volume compensation balloon 44, which can be kept to a small volume of liquid due to the low overall volume of liquid. In the constructed embodiment the length of the shaft 32 was 7.5 inches from the handle to the distal tip
20 (dimension A in FIGURE 2). The transducer mount assembly 40 is contained within the distal 1.5 inches of that length (dimension B in FIGURE 2). Thus, there is only 6 cc of liquid in the forward half of the probe shaft 32, and only 6.3 cc of liquid in the
25 entire shaft. Ninety-five percent of the liquid is in close proximity to the transducer array, located as it is in the distal 20% of the probe shaft. With so little liquid in the shaft and so little liquid in the forward half of the probe shaft, and the motor
30 located in the handle, the center of gravity 62 of the probe handle and shaft is located in the handle, a full inch behind the handle/shaft interface (dimension C in FIGURE 2). With the center of gravity located in the handle the probe is much
35 easier and more comfortable to manipulate during use.

ATL-360

In addition to the small amount of fluid needed in the forward section of the shaft, the embodiment of FIGURES 3 and 4 employ additional measures to reduce the amount of liquid and the weight of the probe shaft 32. Only critical wear surfaces within the shaft 32, such as the drive shaft 50, the gears 54, and pivot points for the transducer cradle are made of stainless steel. Selected fasteners and fittings are also made of stainless steel. Other components within the shaft are made of lighter materials with a density lighter than that of stainless steel. The transducer cradle 48 is made of three pieces of aluminum and is tapered on the sides which are the leading edges as the cradle travels through the liquid. The tapering on either side causes the cradle to move more easily through the liquid with less resistance. The space behind the transducer array and backing is not hollow but is filled so as to displace volume that would otherwise be occupied by liquid, further reducing the liquid needed in the distal end of the probe. The main body of the transducer mount assembly 40 is also made of aluminum, as is the isolation tube 52. The volume compensation balloon 44 is made of a thin plastic. The transducer array and its backing are made of material customarily used for those purposes such as piezoelectric ceramic and epoxy. This use of lightweight materials enables a constructed embodiment of the present invention including the probe shaft and handle to weigh only 250 grams, compared to the 400 gram weights of prior art probes.

ATL-360

WHAT IS CLAIMED IS:

1. 1. An ultrasonic intracavity probe for scanning a volumetric region from within the body comprising:
 - a handle section to be held during use of the probe; and
 - a shaft section having a distal end which is to be inserted into a body cavity during use of the probe;
 - a pivotally mounted array transducer located in the distal end of the shaft section;
 - a motor located in the handle section;
 - a drive mechanism coupled to the motor and the array transducer which acts to move the array transducer during scanning; and
 - a liquid bath located in the distal end of the shaft, a portion of which is located between the array transducer and the distal end of the shaft during scanning,wherein the center of gravity of the probe is located in the handle section.
2. The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly located in the distal end of the shaft section, the array transducer being pivotally mounted to the transducer mount assembly,
 - wherein the liquid bath is located within the transducer mount assembly.
3. The ultrasonic intracavity probe of Claim 2, wherein the transducer mount assembly has a proximal termination within three inches of the distal end of the shaft section,

ATL-360

wherein 75% of the liquid bath is contained within the transducer mount assembly.

5 4. The ultrasonic intracavity probe of Claim 3, wherein the transducer mount assembly has a proximal termination within one and one-half inches of the distal end of the shaft section.

10 5. The ultrasonic intracavity probe of Claim 4, wherein 90% of the liquid bath is contained within the transducer mount assembly.

15 6. The ultrasonic intracavity probe of Claim 1, wherein the liquid bath has a volume of less than 25 cc of liquid.

20 7. The ultrasonic intracavity probe of Claim 6, wherein the liquid bath has a volume of less than 10 cc of liquid.

 8. The ultrasonic intracavity probe of Claim 7, wherein the liquid bath has a volume of approximately 6 cc of liquid.

25 9. The ultrasonic intracavity probe of Claim 1, wherein 90% of the liquid bath is located in the most distal 25% of the length of the shaft section.

30 10. The ultrasonic intracavity probe of Claim 9, wherein the liquid bath has a volume of less than 10 cc of liquid.

35 11. The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly having a main body and located in the distal end of

ATL-360

the shaft section, the array transducer being
pivotally mounted to the transducer mount assembly,
the main body of the transducer mount assembly being
formed of a material which is lighter than stainless
steel.

12. The ultrasonic intracavity probe of Claim
11, wherein the array transducer is pivotally mounted
to the transducer mount assembly by a transducer
cradle,

wherein the transducer cradle is made of a
material which is lighter than stainless steel.

13. The ultrasonic intracavity probe of Claim
12, wherein the transducer cradle includes a solid
body located behind the array transducer which
displaces volume in the transducer mount assembly
that would otherwise be occupied by liquid.

14. The ultrasonic intracavity probe of Claim
12, wherein the transducer cradle is tapered so as to
pass more easily through the liquid bath.

15. The ultrasonic intracavity probe of Claim
11, wherein the transducer mount assembly includes
wear surfaces which made of stainless steel.

16. The ultrasonic intracavity probe of Claim
15, wherein the wear surfaces are part of the drive
mechanism.

17. The ultrasonic intracavity probe of Claim
11, wherein the weight of the probe is less than 400
grams.

ATL-360

18. The ultrasonic intracavity probe of Claim 17, wherein the weight of the probe is less than 300 grams.

5 19. The ultrasonic intracavity probe of Claim 18, wherein the weight of the probe is approximately 250 grams.

10 20. The ultrasonic intracavity probe of Claim 18, wherein the only components of the shaft which are made of a material at least equal to the density of stainless steel are components of the drive mechanism.

ATL-360

ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING

Abstract of the disclosure:

5 An intracavity ultrasound probe includes a
pivotaly mounted array transducer which is
oscillated to scan a volumetric region from within
the body. The transducer is oscillated by a motor
located in the probe handle. The array transducer is
10 immersed in a liquid which acoustically couples
ultrasonic energy between the elements of the
transducer and the body. The acoustic coupling
liquid is located in the distal tip of the probe
shaft, where only 6 cc of liquid is required. The
15 small amount of liquid reduces the weight of the
shaft of the probe so that the center of gravity of
the probe is in the handle, making the probe
comfortable and easy to manipulate. The majority of
parts in the probe shaft are made of aluminum or
20 other low density materials, keeping the overall
weight of the probe to about 250 grams.

ATL-360

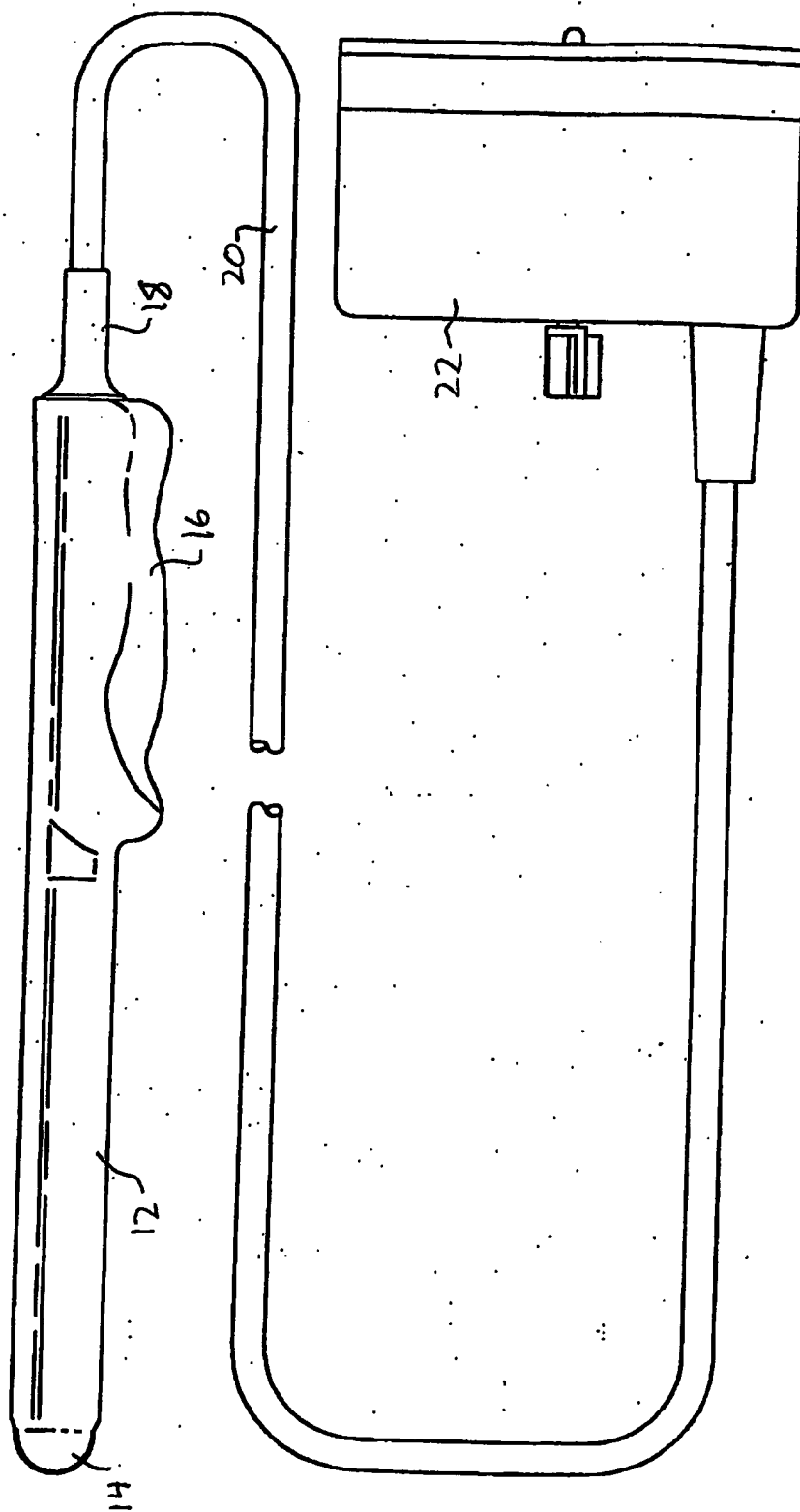


FIG. 1

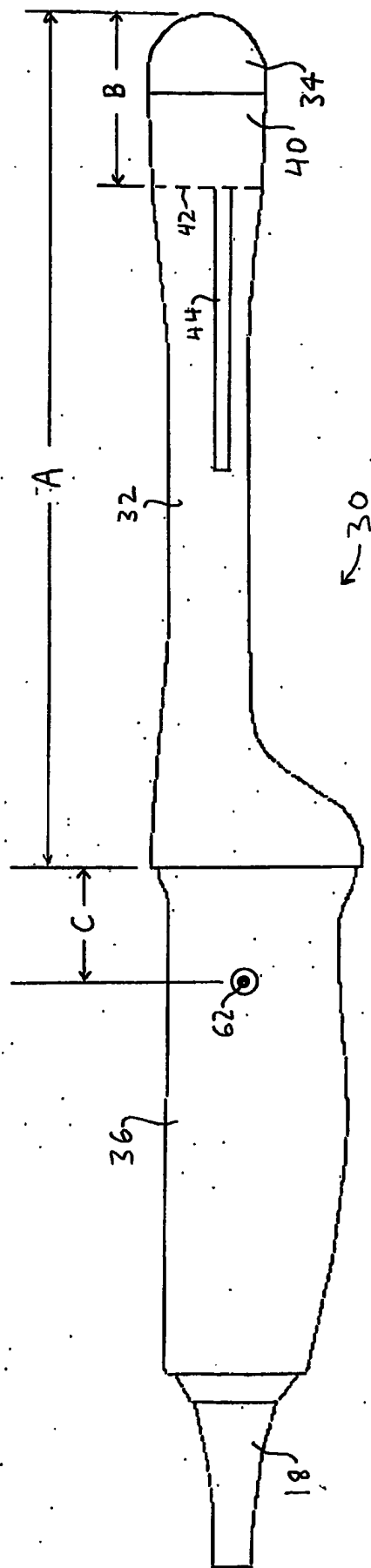


FIG. 2

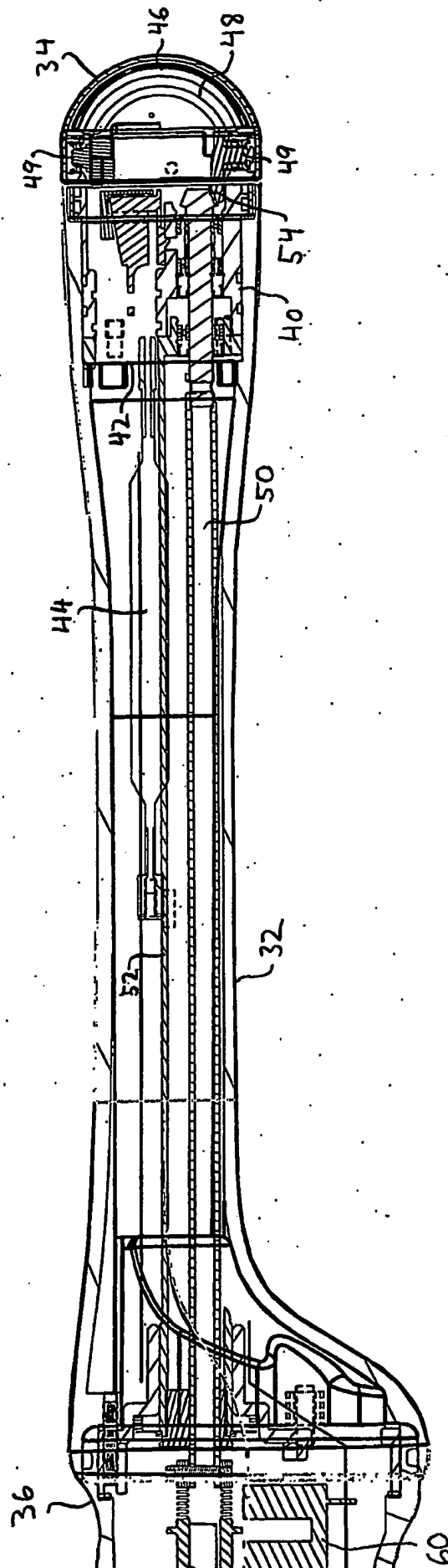


FIG. 3

FIG. 4

